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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/891,750 | 06/26/2001 | Kevin Joseph Moriarty | QA0239ACIP | 2728 |
| 75 | 90 01/04/2002 | | | |
| Marla J. Mathias | | | EXAMINER | |
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| Patent Department | | | | |
| P.O. Box 4000 | | | | |
| Princeton, NJ 08543-4000 | | | ART UNIT | PAPER NUMBER |
| | | | 1624 | |

DATE MAILED: 01/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/891,750 Applicant(s)

Art Unit

1624

Moriarty et al.



Venkataraman Balasubramanian -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on _____ 2b) X This action is non-final. 2a) This action is FINAL. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213. Disposition of Claims 4) X Claim(s) 1-51 is/are pending in the application. 4a) Of the above, claim(s) _______ is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) is/are rejected. 7) Claim(s) _____ _____ is/are objected to. 8) X Claims 1-51 are subject to restriction and/or election requirement. **Application Papers** 9) The specification is objected to by the Examiner. ___ is/are objected to by the Examiner. 10) ☐ The drawing(s) filed on is: a) \square approved b) \square disapproved. 11) The proposed drawing correction filed on 12) The oath or declaration is objected to by the Examiner. Priority under 35 U.S.C. § 119 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d). a) \square All b) \square Some* c) \square None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). *See the attached detailed Office action for a list of the certified copies not received. 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). Attachment(s) 15) Notice of References Cited (PTO-892) 18) Interview Summary (PTO-413) Paper No(s). 16) Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) Notice of Informal Patent Application (PTO-152) 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s). 20) Other:

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DETAILED ACTION

Claims 1-51 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7, 12, 14-17 and 31-51, drawn to compound of formula I wherein X, Y and W are nitrogens, namely triazine, and composition, classified in class 544, subclasses 196,197,208,209, 213, 219, class 514, subclass 241.
- II. Claims 1-3, 8-11,13, 14-17, drawn to compound of formula I wherein two of the X, Y and W are nitrogens and the other carbon, namely pyrimidine, and composition, classified in class 544, subclasses 298, 299, 315, 319, 322, 323, 326, 327, class 514 subclasses 256,269 and 275.
- III. Claims 1 and 14-17, drawn to wherein one of the X, Y and W is a nitrogen and the other two carbons, namely pyridine, composition and method of use, classified in class 546, subclasses 290, 296, 297, class 514, subclasses 345 and 349.
- IV. Claims 1 and 14-17, drawn to wherein all three of the X, Y and W are carbons, namely benzene, composition classified in class 564, subclass 306, class 568, subclasses 67, 584 and 585, V.Claims 18-30, drawn to various method of use of the compound of formula I, class 514, subclasses 647, 712, 717 etc.

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V. Claims 18-30, drawn to various method of use of compound of formula I with various mode of action for treating various diseases class 514, subclasses 241, 256, 269, 275, 345, 349, 647, 712, 717 etc.

If invention I or II or IV is elected, applicants may elect a specific method of use with a specific mode of action for a specific disease(s).

If invention V is elected applicants should elect a specific X, Y, W and a specific method of use with a specific mode of action for a specific disease(s).

The inventions are distinct, each from the other because of the following reasons:

Inventions I-IV are independent and distinct from each other because they are directed to structurally dissimilar compounds that lack common core such s triazine vs pyrimidine vs pyridine vs benzene core. Consequently, the groups have different classifications and require separate prior art searches. They can be made and used independently. Art which may render obvious or anticipate one of the groups would not necessarily do the same for the other group as evidenced by the references cited in the Information Disclosure Statement provided by the applicants. Each can support a patent, as the compounds of each group are capable of being utilized alone not in combination with other members listed in the Markush group. Placing all such compounds into the same claims is proper to scientific classification as they are separately classified and require separate searches.

Inventions I-IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially



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different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the compound of each invention may be used to treat disease mediated by TNF-αor p-38 or any other mediators disclosed in the prior art. Similarly, the process for using the product as claimed can be practiced with another materially different product as evidenced by instant claims which embrace, triazine, pyrimidine, pyridine and benzene compounds for the same method of use as well as structurally related prior art compounds.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Due to distinct nature of each of the inventions, the restriction is set forth in writing.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (703)

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305-1674. The examiner can normally be reached on Monday through Thursday from

8.00 AM to 5.30 PM.

The fax phone number for the organization where this application or proceeding is assigned (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

V. Bala on bamaman Venkataraman Balasubramanian

1/3/2002

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